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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048.116	02/27/2002	Nicolas Glaichenhaus	1721-47	6350

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,116	GLAICHENHAUS ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/22/05 & 4/17/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-39* is/are pending in the application.

4a) Of the above claim(s) *29-31 and 39* is/are withdrawn from consideration.

5)☒ Claim(s) *12,15,16 and 21-22 and 24* is/are allowed.

6)☒ Claim(s) *13 and 32-38* is/are rejected.

7)☒ Claim(s) *14,17-20,23 and 25-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

DETAILED ACTION

1. Applicant's amendment filed 12/22/05 and Applicant's response filed 4/17/06 are acknowledged and have been entered.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this Office Action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with both these requirements in the time period set forth in this Office Action will be held non-responsive.

3. Applicant is required under 37 C.F.R. 1.821(d) to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification (for example, the complementary coding strand disclosed in Figure 1).

4. Applicant is reminded of Applicant's election of Group II (claims 4-6), and species of "cDNA construct of Example 1 which is also provided in Figure 1 providing the cDNA sequence from position 420 to 1940 as well as the coated [coded] peptide" in Applicant's responses 12/6/04 and 4/11/05, respectively.

Upon consideration of the prior art, the Examiner has extended the search to include additional species. The claims are currently being examined as they read on the SEQ ID NO recited in instant claims 13-28 and the nucleotide sequences recited in instant claims 32-38, and expression vector and host cell thereof.

Accordingly, newly added claims 29-31 and 39 (corresponding to non-elected Group I) are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant's request for reconsideration and withdrawal of the restriction requirement has been fully considered by the Examiner, but is not persuasive.

It is the Examiner's position that the restriction requirement mailed 10/6/04 demonstrated lack of unity over then pending independent claim 11 as enunciated at item #3 of said restriction requirement.

Claims 12-28 and 32-38 are presently being examined.

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

the required "Sequence Listing" is not submitted as an electronic document on compact disc).

6. The disclosure is objected to because of the following informalities: the word "sequences" is missing after "amino acid" and before "encoding" in the replacement paragraphs for the brief description of the drawings for Figures 1 and 3. Appropriate correction is required.

7. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because: there are handwritten changes and because Figure 3 still contains text not in English, *i.e.*, "Site Thrombine." Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The following are new grounds of rejection necessitated by Applicant's amendment filed 12/22/05.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 33-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claim limitations "acidic leucine zipper" and "hinge region" recited in claim 33, "a LACK peptide" recited in claims 34 and 35, "β1" recited in claims 34 and 35, and "basic leucine zipper" recited in claim 35, "a hinge region" recited in instant claim 34, and "a thrombin site" recited in claims 34 and 35 in the context of the said claims are not supported by the disclosure and claims as originally filed.

a. Claim 33 recites a nucleotide sequence comprising in operable combination sequence encoding signal peptide of IA^d, $IA^d\alpha$, an amino acid linker, an acidic leucine zipper, an amino acid linker, a hinge region, a CH2 region of FC and a CH3 region of FC. However, the specification discloses only one acidic leucine zipper in a particular construct comprising in the following order: a signal peptide of IA^d, $IA^d\alpha$, a particular amino acid linker(s) and a particular hinge-CH2-CH3. The instant claim is drawn to a generic construct, whereas support is found for only the species of acidic leucine zipper

consisting of LQALEKENAQLEWELQALEKELAQ disclosed in one species of construct depicted in Figure 1.

b. Claim 35 recites elements of a generic $IA^d\beta$ construct that are not in operable combination, and among said elements is a "basic leucine zipper." The instant claim is drawn to elements not in operable combination that could be joined to make a generic construct, whereas support is found only for the species of basic leucine zipper depicted in Figure 3.

c. Claims 34 and 35 recite "a LACK peptide" in the context of generic constructs or elements of said constructs, whereas the originally filed disclosure is to a particular LACK peptide comprised in one species of construct depicted in Figure 3.

d. Claims 34 and 35 recite "β1" in the context of generic constructs or elements of said constructs, whereas the originally filed disclosure is to the sequence "GNS" (*i.e.,* "β1") comprised in one species of construct depicted in Figure 3.

e. Claims 34 and 35 recite "a thrombin site" in the context of generic constructs or elements of said constructs, whereas the originally filed disclosure is to one particular species of thrombin site comprised in one species of construct depicted in Figure 3.

f. Claim 33 recites "a hinge region" in the context of a generic construct, whereas the disclosure is to a specific species of IgG hinge region, not any hinge region of any protein, comprised in a specific species of construct depicted in Figure 1.

10. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the Applicant had possession at the time of invention of the claimed isolated host cell comprising "a vector comprising ***a*** nucleotide sequence of claim 14" (Examiner emphasis).

The instant claim encompasses an isolated host cell comprising a vector comprising a nucleotide sequence coding for the amino acid sequence of SEQ ID NO: 6 and a vector comprising any portion of the nucleotide sequence of claim 14, *i.e.,* containing any subsequence of the nucleotide sequence of claim 14 flanked by undisclosed sequence

and wherein the subsequence does not encode an $IA^d\alpha$ chain. There is insufficient disclosure in the specification on such a host cell.

The specification discloses that host cells produce chimeric $IA^d\alpha$ chain and chimeric $IA^d\beta$ chain or other chimeric class I or class II MHC α and α chains with the aid of suitable expression vectors (page 3 at lines 16-17, pages 3 at line 4 through page 6 at line 8 and Example 1).

There is no disclosure of a host cell comprising a vector or nucleic acid molecule encoding a full chimeric $IA^d\beta$ chain and an undisclosed portion of a chimeric $IA^d\alpha$ chain flanked by sequence that are not the portions disclosed in operable combination in the nucleic acid sequence of claim 14.

The instant disclosure does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera, including any lipid or portion thereof. Since the disclosure fails to provide sufficient relevant identifying characteristics, and because the genus is highly variant, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed.

11. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to make and use the instant invention, the claimed isolated host cell comprising "a vector comprising ***a*** nucleotide sequence of claim 14" (Examiner emphasis).

The specification has not enabled the breadth of the claimed invention because the instant claim encompasses an isolated host cell comprising a vector comprising a nucleotide sequence coding for the amino acid sequence of SEQ ID NO: 6 and a vector comprising any portion of the nucleotide sequence of claim 14, *i.e.,* containing a subsequence of the nucleotide sequence of claim 14 flanked by undisclosed sequence and wherein the subsequence does not encode an $IA^d\alpha$ chain. The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed isolated host cell can be made and used.

The specification discloses that host cells produce chimeric $IA^d\alpha$ chain and chimeric $IA^d\alpha$ chain or other chimeric class I or class II MHC α and α chains with the aid of suitable expression vectors (page 3 at lines 16-17, pages 3 at line 4 through page 6 at line 8 and Example 1).

There is no disclosure of a host cell comprising a vector or nucleic acid molecule encoding a full chimeric $IA^d\beta$ chain and an undisclosed portion of a chimeric $IA^d\alpha$ chain flanked by sequence that are not the portions disclosed in operable combination in the nucleic acid sequence of claim 14 that would allow the a vector comprising a subsequence of "a" nucleic acid sequence of claim 14 to produce a chimeric class II alpha chain MHC construct that would be capable of binding to the chimeric beta chain construct and functioning in tandem with the chimeric beta chain as a class II MHC molecule. Because of this lack of guidance, the extended experimentation that would be required to determine which additions/deletions would be acceptable to retain functional activity, especially as the fact that the relationship between the sequence of a peptide and its tertiary structure (*i.e.,* its activity) are not well understood and are therefore not predictable (Evidentiary reference Ngo *et al.* The Protein Folding Problem and Tertiary Structure Prediction, Merz & LeGrand, Birkhauser Boston, pages 491-495, 1994, entire article, especially Section 6, paragraph 1), it would require undue experimentation for one of skill in the art to arrive at other amino acid sequences that would have functional activity, and to therefore make the corresponding nucleic acid molecule, vector comprising the nucleic acid molecule and isolated host cell thereof. In other words, since it would require undue experimentation to identify amino acid sequences that have functional activity, it would require undue experimentation to make and use the corresponding sequences to produce the claimed isolated host cell.

There is insufficient guidance in the specification as to how to make and/or use instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 13 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

a. Claim 13 is indefinite in the recitation of "the nucleotide sequence spanning positions 18-1502 of the claim 12" because it is not clear what is meant. It is suggested that Applicant amend said claim to recite "the nucleotide sequence spanning positions 18-1502 of SEQ ID NO: 1" if that is what is meant.

b. Claim 35 is indefinite in the recitation of "or.a nucleotide sequence..." because it is not clear what is meant. There is a period before "a" (a period should end a claim), and the recitation of the limitations following "or .a nucleotide sequence" are separate limitations, *i.e.,* separate nucleic acid sequences rather than a single nucleic acid sequence comprising portions that are operably linked with one another in a particular order.

c. Claims 34 and 35 are indefinite in the recitation of "a nucleotide sequence coding for β1," because it is not clear what is meant.

d. Claims 34 and 35 are indefinite in the recitation of "a nucleotide sequence coding for a LACK peptide," because it is not clear what is meant.

14. For the purpose of prior art rejections, the filing date of the instant claims 33-38 is deemed to be the filing date of the instant application, *i.e.,* 2/27/02, as the parent applications do not support the claimed limitations of the instant application as enunciated at item #9 supra of this Office action.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 33 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/03552 A2 (1/98, Applicant's IDS reference) in view of WO 98/06749 A2 (Applicant's IDS reference), WO 97/28191 A1 (Applicant's IDS reference) and US 6,090,911 (priority to 1997).

WO 98/03552 A2 teaches nucleic acid molecules encoding the chains of dimers or multimers, said dimers or multimers comprised of dimers of MHC class II α chain extracellular regions fused at the carboxy-terminus, including via linker sequence to Ig hinge, CH2, CH3 regions plus MHC class II β chain extracellular regions fused, including via linker sequence, to Ig hinge, CH2, CH3 regions, and additionally comprising nucleic acid sequence encoding leucine zippers. WO 98/03552 A2 teaches that the linker can be a leucine zipper and can be situated after the MHC class II chain before the hinge-CH2-CH3 region. In addition, WO 98/03552 A2 teaches that the nucleic acid sequences of the individual chains may also include the sequence of an antigenic peptide. WO 98/03552 A2 teaches expression vectors such as pCMV4. WO 98/03552 A2 also teaches nucleic acid molecules/expression vectors/host cells thereof, encoding dimers of class I MHC comprising class I MHC extracellular domains, linkers and β2m (such as plasmid pHuActβ2), and prokaryotic host cells (such as *E. coli*) comprising the vector and nucleic acid sequence of the MHC class II chain(s) (see entire document, especially abstract, page 2 at lines 20-35, page 3 at lines 1-35, page 4 at lines 1-36, page 6 at line 1 through page 8 and claims).

WO 98/03552 A2 does not teach the said nucleic acid molecule wherein the MHC class II alpha chain is from IA^d, nor wherein there is a nucleic acid segment encoding a signal peptide at the amino terminus of the nucleic acid molecule, nor wherein the leucine zipper is an acidic leucine zipper.

WO 98/06749 A2 teaches nucleic acid molecules encoding the chains of dimers or multimers, said dimers or multimers comprised of MHC class II α chain extracellular regions fused at the carboxy-terminus, including via linker sequence, to Ig Fc region or portions thereof, plus MHC class II β chain extracellular regions fused including via linker sequence to Ig Fc region. WO 98/06749 A2 teaches leucine zipper between the MHC class II chain and the Ig Fc portions. WO 98/06749 A2 teaches the nucleic acid molecule may encode a secretion signal sequence at the amino terminus, *i.e.*, encodes a signal peptide as recited in instant claim 33. WO 98/06749 A2 teaches use of flexible amino acid residue linkers to insure that there is free rotation between the MHC components and the Ig components such that the geometry of the association between the Ig and leucine zipper components do not constrain or interfere with the geometry of association of the MHC domains when the single chains are paired. WO 98/06749 A2 teaches expression vectors, including plasmid vectors, and prokaryotic or eukaryotic host cells comprising the vector and nucleic acid sequence of the MHC class II chain(s) (see entire document, especially abstract, page 2 at the last paragraph, pages 4 through 7 at line 9, page 7 at lines 10-14, brief description of the drawings for Figures 1-4, Figures 1-4, pages 15 through 19 at line 76, page 30 at lines 1-11, page 39 at lines 13-32 through page 40 at line 23, page 42 at lines 26-31, page 44 at lines 1-5, page 47 at lines 3-8, claims).

WO 97/28191 A1 teaches nucleic acid molecules encoding MHC class II molecules complexed with the Fc region of an Ig heavy chain, expression vectors, including plasmids, comprising the said nucleic acid molecules, and eukaryotic host cells thereof. WO 97/28191 A1 further teaches the class I molecule may be the murine class II MHC molecule IA^d (especially Example 2 on pages 49-55).

US 6,090,911 discloses using an acidic leucine zipper in one component protein chain of a heterodimer and a basic leucine zipper in another component protein of a heterodimer in order to provide intermolecular attraction between heterodimer chains, and to maximize the heterodimer formation (especially column 6 at lines 5-35, column 11 at lines 6-15, column 14 at lines 49-56, claims).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have added a signal peptide to the construct taught by WO 98/03552 A2 and to have separated the leucine zipper portion from the MHC class II alpha chain encoding portion and the hinge-CH2-CH3 portion using flexible linkers such as those taught by WO 98/03552 A2 and by WO 98/06749 A2, but to have used the MHC class II alpha chain from IA^d that is taught by WO 97/28191 A1. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used any leucine zipper, including the acidic leucine zipper disclosed by US 6,090,911.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to make a construct useful for studying mouse MHC class II interactions as taught by WO 97/28191 A1, using the construct forms taught by the combination of WO 98/03552 A2 and WO 98/06749 A2, *i.e.*, adding the signal peptide for secretion as taught by WO 98/03552 A2 and to have separated the leucine zipper portion from the MHC class II alpha chain encoding portion and the hinge-CH2-CH3 portion using flexible linkers such as those taught by WO 98/03552 A2 and by WO 98/06749 A2 to insure that there is free rotation between the MHC components and the Ig components such that the geometry of the association between the Ig and leucine zipper components do not constrain or interfere with the geometry of association of the MHC domains when the single chains are paired as taught by WO 98/06749 A2. One of ordinary skill in the art at the time the invention was made would have been motivated to use the acidic leucine zipper disclosed by US 6,090,911 in order to more effectively heterodimerize the alpha chain with the beta chain because by US 6,090,911 discloses maximization of heterodimer formation using acidic and basic leucine zippers.

17. Claim 14 is objected to because of the following informality: Claim 14 recites "comprising a nucleotide sequence coding for the amino acid sequence encoded by the nucleotide sequence of claim 12 (SEQ ID NO: 2)." SEQ ID NO: 2 is the amino acid sequence, not the nucleotide sequence. It is suggested that Applicant amend said claim to recite "comprising a nucleotide sequence coding for the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of claim 12." " Appropriate correction is required.

18. Claim 23 is objected to because of the following informality: Claim 23recites "comprising a nucleotide sequence coding for the amino acid sequence encoded by the nucleotide sequence of claim 21 (SEQ ID NO: 6)." SEQ ID NO: 6 is the amino acid sequence, not the nucleotide sequence. It is suggested that Applicant amend said claim to recite "comprising a nucleotide sequence coding for the amino acid sequence (SEQ ID NO: 6) encoded by the nucleotide sequence of claim 21." " Appropriate correction is required.

19. Claims 17-20 and 25-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. SEQ ID NO: 1-3 and 5-7 appear to be free of the art.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
July 17, 2006

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of Attachment(s) 6). Other: Notice to Comply with the Sequence Rules.

Notice to Comply	Application No. 10/048,116	Glaichenhaus et al.	
	Examiner Marianne DiBrino	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Applicant must provide SEQ ID NO for sequences disclosed in the specification, for example for the complementary strand disclosed in Figure 1.

Applicant Must Provide:

☒ A ~~n initial or~~ substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ A ~~n initial or~~ substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

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